Message

From: Flowers, Lynn [Flowers.Lynn@epa.gov]
Sent: 5/16/2018 11:41:10 AM
To: Kuhn, Kevin [Kuhn.Kevin@epa.gov]; Vandenberg, John [Vandenberg.John@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Teichman, Kevin [Teichman.Kevin@epa.gov]; Blancato, Jerry [Blancato.Jerry@epa.gov]; Christian, Megan [Christian.Megan@epa.gov]; Bahadori, Tina [Bahadori.Tina@epa.gov]; Sinks, Tom [Sinks.Tom@epa.gov]; Grifo, Francesca [Grifo.Francesca@epa.gov]; Hauchman, Fred [hauchman.fred@epa.gov]; D'Amico, Louis [DAmico.Louis@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]
Subject: FYI - SAB workgroup Pans Pruitt's Science Transparency Rule, Seek SAB Review - memo attached
Attachments: epa2018_0856.pdf

DAILY NEWS

Top Advisors Pan Pruitt's Science Transparency Rule, Seek SAB Review

May 15, 2018

Top EPA science advisors, including Administrator Scott Pruitt's hand-picked chair of the agency's Science Advisory Board (SAB), are strongly criticizing the administrator's controversial plan to require only publicly available research to justify its regulations, charging it will undermine rules' integrity and was developed without adequate review.

"The proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits," an SAB work group said in a May 12 memo recommending the full SAB review the measure.

The work group even warns that the proposed rule "could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts," and suggests several steps to ease the rule's limits to allow for the use of confidential data.

And echoing concerns from EPA staff, environmentalists, states and Democratic lawmakers, the memo warns that the measure was developed without adequate review from the public, the scientific community and others and calls for the full SAB to review the measure.

"Although the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community," the memo says.

"The proposed rule deals with issues of scientific practice and proposes constraints that the agency may apply to the use of scientific studies in particular contexts," the memo says. "As such, this rule deals with a myriad of scientific issues for which the Agency should seek expert advice from [SAB]," it adds.

The work group's May 12 memo is scheduled to be considered by the chartered SAB at its next meeting, slated for May 31-June 1 in Washington, D.C. The board is already scheduled to consider an earlier work group report that calls for the SAB to review Trump EPA plans to roll back three Obama-era climate rules -- for new and existing power plants, as well as new and modified oil and gas sources -- because they concluded EPA may not use adequately peer-reviewed science to justify the plans.

Historically, SAB work groups reviewing EPA regulatory agendas rarely find actions that meet their strict criteria to merit further review, but such calls appear to have become more common.

The latest recommendation for SAB review was issued quickly, weeks after Pruitt signed the measure April 24.

The full board -- with its slate of new members selected by Pruitt -- could reject the work group's advice, but the recommendation still raises the heat on an already controversial proposal.

And while SAB's earlier work group recommending review of the three climate rules contained few Pruitt appointees, the updated membership of the work group recommending full SAB action on the science transparency rule includes its new chairman, Michael Honeycutt, a top Texas state risk assessor, who Pruitt appointed to the post late last year.

The work group also includes John Graham, another Pruitt appointee who led the Bush administration's White House Office of Information and Regulatory Affairs. Graham was instrumental in advancing a controversial risk assessment guidance for federal agencies until it was forced into a critical National Academy of Sciences (NAS) review, which in 2007 recommended that it be dropped.

In a statement to *Inside EPA* the agency replied, SAB "plays an important role in informing EPA actions on policy and regulatory matters. We value the Board's expertise, and we welcome feedback from the chartered panel on areas in which they are interested in getting additional scientific information that is relevant to the rulemaking process."

Proposed Rule

The proposed rule generally bars EPA staff from basing regulatory actions on any science where the underlying data and modeling is not publicly available, though the plan allows the administrator to waive the requirements. The concept is based on controversial legislation long championed by House science committee chairman Lamar Smith (R-TX), which twice passed the House but has failed to advance in the Senate.

Critics charge it is intended largely to block the use of long-standing confidential medical studies that the agency has relied on when setting strict air quality and other health-based standards, though the chemical and pesticide industries have also raised concerns it could affect the use of confidential business information.

Environmentalists are especially concerned that the proposal targets the agency's long-time use of strict, default linear dose-response models, which Republicans and industry groups say result in stricter rules than are needed.
Many observers have warned the measure faces significant legal hurdles, including vague or undefined terminology, statutory mandates likely at odds with the rule and potential violations of administrative law.
The proposal was published in the *Federal Register* April 30 for a 30-day public comment period, though environmentalists, states and Democratic senators have urged the agency to withdraw the proposed rule to consult with the National Academy of Sciences and to extend the comment period by as much as 150 days to allow for such NAS consultation.
EPA staff has also warned that the measure was rushed through intra-agency review without the usual staff and program office input that such significant measures usually receive. As a result, they say it is unclear whether the agency will be able to finalize the proposal in its current form because officials did not create an agency-wide group that would be able to review and respond to the thousands of comments the agency is likely to receive.
The SAB work group memo echoes much of the criticisms, noting that the proposed rule "would limit the use of science based on human subject data and would impose requirements for the analysis of dose-response relationships widely used in risk assessments across a wide range of agency programs."
While acknowledging the value of transparency in underlying data, modeling and approaches, as well as the efforts in multiple science fields to advance transparency, the work group adds that it is not always possible, especially for studies published in the past. "There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate," the work group writes.
The work group adds that the proposed rule "fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods" and "oversimplifies" its argument that it is easy to address confidentiality concerns through existing methods, such as redaction.
And, the memo criticizes the draft rule's efforts to make transparent "the dose response data and models that underlie what we are calling 'pivotal regulatory science'." Rule language on dose-response modeling appears to target EPA's longstanding cancer risk assessment guidance, which as a default directs agency risk assessors to use linear modeling -- assuming no safe exposure -- unless there is biological information directing otherwise.
The work group says that the proposed rule's "requirement of the consideration of multiple dose-response models should explicitly state that this consideration is based on information relevant to the selection of the most scientifically-appropriate model(s) such as biological plausibility, mode of action, or mechanism of action. Deviations from the use of default models should be evaluated on a case-by-case basis and have adequate scientific justification for use of an alternative model better supported by the chemical-specific data."
The work group also suggests several other steps EPA take to soften the proposal, including limiting its application to future studies rather than those already designed or published.
"It might be easier to accomplish the rule's objectives if the focus were on future studies rather than on studies that are already designed and published with terms that make complete transparency difficult or impossible to accomplish."
"It might also be easier if the rule took into account reasonable areas for accommodation or exception in situations for which it is not possible to release a data set publicly either entirely, or without revision, for legitimate reasons pertaining to the use, for example, of human subject data," the memo adds. -- *Maria Hegstad*(mhegstad@iwpnews.com)

-----Original Appointment-----
From: Kuhn, Kevin
Sent: Thursday, May 10, 2018 3:19 PM
To: Kuhn, Kevin; Vandenberg, John; Bussard, David; Teichman, Kevin; Blancato, Jerry; Flowers, Lynn; Christian, Megan; Bahadori, Tina; Sinks, Tom; Grifo, Francesca; Hauchman, Fred; D'Amico, Louis; Doa, Maria
Subject: General Discussion - small group
When: Tuesday, May 15, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomRRB41107-1; DCRoomRRB41107-2; Call in **Ex. 6 Personal Privacy (PP)**

Please find relevant materials for the conversation at the following SharePoint site:

Ex. 6 Personal Privacy (PP)